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|-------------------------------|----------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 09/843,221 | KOSTENUK ET AL. | |
| | Examiner | Art Unit | |
| | Christopher Nichols, Ph.D. | 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5 November 2003.
2. ☒ The allowed claim(s) is/are 80-103.
3. ☒ The drawings filed on 05 November 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Amendment and Response filed 5 November 2003 has been received and entered in full. Claims **31**, **36**, and **38** have been amended. Claims **39-79** have been cancelled. Claims **1-38** are currently pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. All Rejections and Objections not maintained herein are hereby *withdrawn*.

Withdrawn Objections And/Or Rejections

4. The Objection to the Specification And/Or Drawings as set forth at pp. 3-4 ¶4-7 of the previous Office Action (5 May 2003) is *withdrawn* in view of Applicant's amendments (5 November 2003).
5. The rejection of claims **1-38** under 35 U.S.C. §101 as a "product of nature" as set forth at pp. 4 ¶9 of the previous Office Action (5 May 2003) is *withdrawn* in view of Applicant's arguments (5 November 2003).
6. The Rejection of claims **31**, **36**, and **38** under 35 U.S.C. §112 ¶2 as set forth at pp. 4-5 ¶10 of the previous Office Action (5 May 2003) is *withdrawn* in view of Applicant's amendments (5 November 2003).
7. The Rejection of claims **1-38** under 35 U.S.C. §102(b) as set forth at pp. 5-8 ¶11-18 of the previous Office Action (5 May 2003) is *withdrawn* in view of Applicant's arguments (5 November 2003).

8. The Rejection of claims **1-38** under 35 U.S.C. §102(b) as set forth at pp. 5-6 ¶11-12 of the previous Office Action (5 May 2003) is *withdrawn* in view of Applicant's arguments (5 November 2003).
9. The Rejection of claims **1-38** under 35 U.S.C. §102(b) as set forth at pp. 6-7 ¶13-14 of the previous Office Action (5 May 2003) is *withdrawn* in view of Applicant's arguments (5 November 2003).
10. The Rejection of claims **2-38** under 35 U.S.C. §102(b) as set forth at pp. 7-8 ¶15-16 of the previous Office Action (5 May 2003) is *withdrawn in part* in view of Applicant's arguments (5 November 2003).
11. The Rejection of claims **1-38** under 35 U.S.C. §102(b) as set forth at pp. 8 ¶17-18 of the previous Office Action (5 May 2003) is *withdrawn* in view of Applicant's arguments (5 November 2003).

Oath/Declaration

12. Applicant is now required to submit a substitute declaration or oath to correct the deficiencies set forth as set forth at pp. 3 ¶3 of the previous Office Action (5 May 2003). The substitute oath or declaration must be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability" (PTO-37). Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136. Failure to timely file the substitute declaration (or oath) will result in **ABANDONMENT** of the application. The transmittal letter accompanying the declaration (or oath) should indicate the date of the "Notice of Allowance" (PTOL-85) and the application number in the upper right hand corner.

EXAMINER'S AMENDMENT

13. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

14. In the Specification:

On page 11 line 21 add "3A, 3B, 3C" after Figure.

On page 43 line 23 add "(SEQ ID NO: 6)" after "Gly-Gly-Gly-Lys-Gly-Gly-Gly"

On page 54 line 16 replace "mas" with "mass."

15. In the claims:

Claims 1-79 (Cancelled)

Claim 80 (New) A polypeptide comprising a parathyroid hormone (PTH) peptide and a Fc domain, wherein said Fc domain is covalently attached to the C-terminus of said PTH peptide.

Claim 81 (New) The polypeptide of claim 80 further comprising a linker attaching said Fc domain to said PTH peptide.

Claim 82 (New) The polypeptide of claim 80, wherein said Fc domain is an IgG Fc domain.

Claim 83 (New) The polypeptide of claim 80, wherein said Fc domain is an IgG1 Fc domain.

Claim 84 (New) The polypeptide of claim 80, wherein said Fc domain comprises the sequence of SEQ ID NO: 2.

Claim 85 (New) The polypeptide of claim 80, wherein said PTH peptide is PTH-(1-84) or a fragment thereof having PTH activity.

Claim 86 (New) The polypeptide of claim 80, wherein said PTH peptide is modified with one or more conservative amino acid substitutions.

Claim 87 (New) The polypeptide of claim 85, wherein said PTH peptide is selected from the group consisting of PTH-(7-84), PTH-(1-44), PTH-(1-38), PTH-(2-38), PTH-(1-34), PTH-(7-34), PTH-(1-31), PTH-(1-30), PTH-(7-30), PTH-(1-29), and PTH-(1-28).

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Claim 88 (New) The polypeptide of claim 80, wherein said PTH peptide is selected from the group consisting of SEQ ID NO: 161, SEQ ID NO: 162, SEQ ID NO: 163, SEQ ID NO: 164, SEQ ID NO: 165, SEQ ID NO: 166, SEQ ID NO: 167, and SEQ ID NO: 168.

Claim 89 (New) A polypeptide comprising a parathyroid hormone-related protein (PTHrP) peptide and a Fc domain, wherein said Fc domain is covalently attached to the C-terminus of PTHrP.

Claim 90 (New) The polypeptide of claim 89 further comprising a linker attaching said Fc domain to said PTHrP peptide.

Claim 91 (New) The polypeptide of claim 89, wherein said Fc domain is an IgG Fc domain.

Claim 92 (New) The polypeptide of claim 89, wherein said Fc domain is an IgG1 Fc domain.

Claim 93 (New) The polypeptide of claim 89, wherein said Fc domain comprises the sequence of SEQ ID NO: 2.

Claim 94 (New) The polypeptide of claim 89, wherein said PTHrP peptide is PTHrP-(1-86) or a fragment thereof having PTHrP activity.

Claim 95 (New) The polypeptide of claim 89, wherein said PTHrP peptide is modified with one or more conservative amino acid substitutions.

Claim 96 (New) The polypeptide of claim 89, wherein said PTHrP peptide is selected from the group consisting of PTHrP-(1-36), PTHrP-(1-34), PTHrP-(7-34), [Asn10, Leu11] PTHrP-(7-34), PTHrP-(8-34), PTHrP-(1-30), PTHrP-(7-30), and PTHrP-(8-30).

Claim 97 (New) The polypeptide of claim 86, wherein said PTHrP peptide is SEQ ID NO: 169.

Claim 98 (New) A polypeptide comprising a tuberoinfundibular peptide of 39 residues (TIP39 peptide) and a Fc domain, wherein said Fc domain is covalently attached to the C-terminus of said TIP39 peptide.

Claim 99 (New) The polypeptide of claim 98 further comprising a linker attaching said Fc domain to said TIP39 peptide.

Claim 100 (New) The polypeptide of claim 99, wherein said Fc domain is an IgG Fc domain.

Claim 101 (New) The polypeptide of claim 99, wherein said Fc domain is an IgG1 Fc domain.

Claim 102 (New) The polypeptide of claim 99, wherein said Fc domain comprises the sequence of SEQ ID NO: 2.

Claim 103 (New) The polypeptide of claim 95, wherein said TIP39 peptide is SEQ ID NO: 170.

16. Authorization for this examiner's amendment was given in a telephone interview with Robert Winter on 27 January 2004.

EXAMINER'S REASONS FOR ALLOWANCE

17. The following is an examiner's statement of reasons for allowance:

18. Usdin *et al.* (November 1999) "TIP39: a new neuropeptide and PTH2-receptor agonist from hypothalamus." Nature Neuroscience 2(11): 941-943 (**IDS**) defines TIP39 as "tuberoinfundibular peptide of 39 residues" and teaches that it is a potent and selective agonist of the PTH2-R (pp. 941). Therefore the Examiner included the full name of TIP39 in claim 98 for purpose of definition only.

19. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Summary

20. Claims **80-103** are hereby allowed.

21. The Examiner acknowledges that acceptance of the above Examiner's Amendment does not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

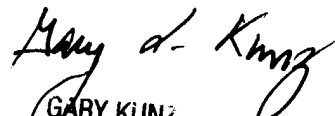
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
January 29, 2004


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600